

REMARKS

Applicants thank the Examiner for granting the Applicants' representative with an opportunity to discuss the present submission in a telephonic interview on January 12, 2004. This Reply reiterates the discussions held during the interview with regard to the claim amendments and description of support for claim terms. The amendment to the specification was not discussed during the interview.

Amendment to the Specification

Applicants amend the specification at page 11, to shift text of lines 4 and 5 below the first scheme showing the reaction of HA with NEA, and before the following scheme, showing the reaction of the biopolymer having an aldehyde group with the disulfide compound:



Applicants respectfully submit that this amendment does not introduce new matter.

Claims rejection under 35 USC §112, first paragraph:

Claims 29-44, 55 and 56 are rejected as failing to comply with the written description requirement. Specifically, The examiner questions support for the limitation R being an oxygen in claim 29, or imino in claim 37, for M being 2-(3-nitro-2-pyridine) in claims 33 and 41, for LSSM being 2-(3-nitro-2-pyridine)sulphenyl)-ethylamine in claims 34 and 42 and for the degree of modifications in claims 55 and 56. Applicants respectfully submit that the description provides adequate support for the groups as defined in the claims.

Verbatim description of claimed subject matter is not required to fulfill the requirements of section 112, so long as the specification reasonably conveys to a skilled artisan that applicants had possession of the invention. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 39 USPQ2d 1895 (Fed. Cir. 1996); *In re Kaslow*, 707 F.2d 1366, 217 USPQ 1089 (Fed Cir 1983). Applicants

respectfully submit that the specification reasonably convey to a skilled artisan that applicants were in possession of the invention as claimed.

While verbatim recitation of the objected groups in claims 29, 33, 34, 37, 41 and 42 objected by the examiner may not be found in the specification, Applicants respectfully submit that these groups are reasonably apparent in the specification when read in context with the description, the several schemes and examples, that these groups were contemplated by the applicants at the time of filing and would be readily appreciated by a skilled artisan as falling within the purview of the claims as pending in this application. Applicants particularly point out how adequate support is found in the description for the objected groups as defined in the above claims as follows:

- Claim 29: on page 10, line 23 of the specification, a reaction scheme shows how the claimed modified polymer G-COR-L-SSM may be prepared from two components, the biopolymer with an acid moiety G-COOH and the precursor R-L-SSM. The precursor RLSSM is described on page 10, lines 1-11. In that passage the moiety R is described as being an amino, **hydroxyl** or carbonyl group. It is within the knowledge of the skilled artisan to understand that when an acid (G-COOH) is reacted with an alcohol (RLSSM where R is an hydroxyl) the product formed is an ester where the bridging atom is now an oxygen (G-COR-L-SSM, with R = O). Applicants kindly draw the Examiner's attention to the non restrictive language at page 10, line 24, where R is specified only as to the *preferred* embodiment and thus not excluding the previously defined embodiments of page 10, line 5. Thus applicants respectfully submit that the feature R being an oxygen is adequately described in the application as applied to the claimed structure of claim 29 and would be readily appreciated by the skilled artisan. Accordingly, applicants kindly request withdrawal of this rejection.
- Claim 37: At the bottom of page 11 of the specification, a reaction scheme shows how the claimed modified polymer G-C-R-L-S-S-M may be prepared from two components, the biopolymer with an aldehyde moiety G-CHO, and the precursor R-L-S-S-M. On page 12 line 1, the variable G,R,L,S,M are said to be as specified previously, i.e. including R being an

amino for RLSSM as defined on page 10, line 5. It is within the knowledge of the skilled artisan to understand that when an aldehyde (G-CHO) is reacted with an amino group the product formed is an imine, i.e. where R is an imino group. This reaction is further illustrated on page 12, line 5 onwards, with a preferred embodiment, where hyaluronic acid is selected for the biopolymer and 3-nitro-2-pyridinesulfenyl-ethylamine for the disulfide compound. The third structure below line 5 actually shows the imino group thus formed by reaction of the amine on the aldehyde. The last step described on page 12 shows the reduction of the imino group with sodium borohydride to form the amine. On page 12, lines 10-14, the process is described as forming the Schiff base which is well known in the art to contain the imino group. Thus applicants respectfully submit that the feature R being an imino is adequately described in the application as applied to the claimed structure of claim 37 and would be readily appreciated by the skilled artisan. Accordingly, applicants kindly request withdrawal of this rejection.

- Claims 33, and 41: These claims further define the variable M as being 2-(3-nitro-pyridine). On page 9, lines 10-11, the applicants identified a preferred embodiment for the organic disulfide precursor R-L-SS-M as being 3-nitro-2-pyridinesulfenyl-ethylamine. From that structure, it is evident that the moiety M is attached to the sulfenyl group by the 2 position of the 3-nitro-pyridine, hence 2-(3-nitro-pyridine).
- Claims 34 and 42: These claims are amended to define the moiety RLSSM as being (3-nitro-2-pyridinesulfenyl)-ethylamine. On page 9, lines 10-11, the applicants identified a preferred embodiment for the organic disulfide precursor R-L-SS-M as being 3-nitro-2-pyridinesulfenyl-ethylamine. At the bottom of page 9 a scheme shows the preparation of this precursor and its chemical structure.
- Claims 55: Verbatim support for the recitation of the preferred degree of modification of the polymer can be found in the specification at least in the Examples 2, 3 and 4, which recited in the title preceding each example as follows

- On page 18, lines 4-5: "Example 2: synthesis of HA-NEA with 1%-2% NEA modification."
- On page 18, lines 17-18: "Example 3: synthesis of HA-NEA with 15%-20% NEA modification."
- On page 19, lines 1-2: "Example 4: synthesis of HA-NEA with 40%-50% NEA modification."
- Claim 56. Verbatim support for the recitation of the preferred degree of modification of the polymer can be found in the specification at least in the Examples 9 and 10, which recited in the title preceding each example as follows.
 - On page 21, lines 1-2: "Example 9: Synthesis of End-linked HA-NEA with 35% NEA modification."
 - On page 21, lines 11-12: "Example 10: Synthesis of End-linked HA-NEA with 50% NEA modification."

Rejection of Claims under §112, Second Paragraph:

Claims 34, 36, 42 and 44 are rejected under 35 USC §112, second paragraph as being indefinite.

1. Claims 34 and 42 are said to be unclear for failing to further define the parameter of the formula recited in respective claims 29 and 37. Applicants have amended the claims to recite terms having antecedent basis.

2. Claims 36 and 44 are said to be unclear in the recitation of "normal or iso-substituted alkyl spacer." Applicants have deleted these claims without prejudice and without surrendering the breadth covered by the genus term "alkyl" in the independent claims.

Applicants believe these amendments comply with the Examiner's requests and thus respectfully request that this rejection be withdrawn.